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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,457	JANSEN ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 2-23, 33-50, 52-55 and 59-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 24-32, 51 and 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4/9/02</u> | 6) <input type="checkbox"/> Other: |

Detailed Action

Status of Application, Amendments, and/or Claims

Applicant's election of Invention II (Claims 24-32, 51 and 56-58), with Species *HCN1* of hyperpolarization-activated cation channel (21 October 2003), is acknowledged. In addition, Applicant traversed the Restriction on the following grounds: 1) Independent claims should be examined if their dependent claims are examined; 2) There is no serious burden on the examiner to examine all claims together; 3) examination of two or more inventions causes delays and added expense to the applicants; and, 4) "duplicative examination by the Examiner." However, Invention I and Invention II were properly restricted as separate inventions because they are directed to different methods and products and because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. Furthermore, while it is *not* true that Independent claims must be examined along with their dependent claims, Claim 1 is general enough so that it should be a part of both Groups I and II. Therefore Claim 1 will be rejoined with elected Claims 24-32, 51 and 56-58.

Claims 1, 24-32, 51 and 56-58 are under examination in the Instant Application.

Informalities

Specification

The disclosure is objected to because of the following informalities:

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Continuity

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76). In addition, the Declaration lists application 09/779,587 as *Abandoned*, when its status is *Pending*.

Claim Rejections/Objections

Claim Objections

Claims 24, 25, 51 and 56-58 are objected to for depending from non-elected inventions. Appropriate correction is required.

Claim 51 is objected to for reciting non-elected inventions (e.g., HCN2, HCN3, HCN4 and KAT1).

35 USC § 112, first paragraph – Written Description.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 24-32, 51 and 56-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 1, 24-32, 51 and 56-58 are directed to methods of using a FLIPR assay to test ligands of the *HCN1* channel. The claims recite use of a polypeptide cation channel transfected into cells, methods of recording the membrane potential of the cells and use of potential-sensitive dyes to test ligands of the *HCN1* channel.

The specification teaches use of the *HCN1* polypeptide in a modified FLIPR assay in which an iso-osmolar sodium-ion-free buffer is used to create a standard baseline environment. However, the specification does not teach functional or structural characteristics of the polypeptide used for the claimed methods. The description of one polypeptide *HCN1* channel is not adequate written description of an entire genus of functionally equivalent polypeptides. Furthermore, the structure and the amino acid sequence of the *HCN1* channel is not disclosed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

With the exception of what is known in the art about *HCN* and what is disclosed in the Specification about other *HCN* polypeptides, the skilled artisan cannot envision the detailed chemical structure of the encompassed *HCN1*, and therefore, would not know how to use it.

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Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of use. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, use of an isolated polypeptide molecule comprising a fully disclosed sequence or SEQ ID NO, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections- 35 USC § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being unpatentable over Krahn, et al, 2002 (United States Patent 6,420,183). Krahn, et al. disclose a method of detecting and quantifying changes in living cells, using a FLIPR plate-reader and container(s) each with a cell-layer on the bottom and a supernatant solution comprised of ligand and two fluorescent molecules differing in energy levels. Since their invention reads on "biological cells," it encompasses cells comprising the HCN channel as shown in Claim 1 of the instant Application. This Patent also meets the limitations of claim 1 wherein a change in membrane potential indicates the presence of at least one substance in the sample that modulates the activity of the cation channel, because the claimed methods in Patent 6,420,183 can be used for detecting just such changes in cell function and ligand/receptor interactions are specifically referred to in Claims 20 and 24.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 is rendered indefinite because of the phrase "high-throughput" since "high" is a conditional term. The phrase "high-throughput" is used extensively in the literature to describe a screening process that is significantly faster than conventional methods and is in fact often automated. However, the term as used in Claim 32 does not indicate in numerical terms the

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relative speed of the claimed process. The metes and bounds of the claim, therefore, cannot be ascertained. This rejection can be overcome by supplying specific conditions supported by the specification, which the Applicants consider "high-throughput" or by removing the indefinite phrase.

Conclusion: Claims 1, 24-32, 51 and 56-58 are rejected for the reasons recited above.

Claims 24, 25, 51 and 56-58 are objected to.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

1/17/04


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